

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION)	
_____)	MDL NO. 1203
)	
THIS DOCUMENT RELATES TO:)	
)	
SHEILA BROWN, et al.)	
)	CIVIL ACTION NO. 99-20593
v.)	
)	
AMERICAN HOME PRODUCTS CORPORATION)	2:16 MD 1203

MEMORANDUM AND PRETRIAL ORDER NO.

Bartle, C.J.

May 16, 2007

Nellie McCary ("Ms. McCary" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth, Inc.,¹ seeks benefits from the AHP Settlement Trust ("Trust").² Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").³

1. Prior to March 11, 2002, Wyeth, Inc. was known as American Home Products Corporation.

2. Philip McCary, Ms. McCary's spouse, also has submitted a derivative claim for benefits.

3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their

(continued...)

To seek Matrix Benefits, a claimant must submit a completed Green Form to the Trust. The Green Form consists of three parts. Part I of the Green Form is to be completed by the claimant or the claimant's representative. Part II is to be completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria in the Settlement Agreement. Finally, Part III is to be completed by the claimant's attorney if he or she is represented.

In February 2002, claimant submitted a completed Green Form to the Trust signed by her attesting physician Michael J. Liston, M.D. Dr. Liston is no stranger to this litigation. As we have previously noted, in total he has signed more than 1,600 Green Forms on behalf of claimants seeking Matrix Benefits. See Pretrial Order ("PTO") No. 6339 at 3 (May 25, 2006). Based on an echocardiogram dated October 27, 2001, Dr. Liston attested in Part II of Ms. McCary's Green Form that she suffered from

3(...continued)

medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period, or who took the drugs for 60 days or less, or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these diet drugs.

moderate mitral regurgitation, an abnormal left atrial dimension, and an ejection fraction in the range of 40% to 49%. Based on such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of \$497,928.

In the report of claimant's echocardiogram, Dr. Liston stated that Ms. McCary had "moderate mitral insufficiency with a regurgitant jet measuring 29% of [the] total left atrial dimension." Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22. Dr. Liston further opined that claimant had mild left atrial enlargement and her "left atrium is mildly dilated measuring 4.6 cm in the parasternal view and 5.32 cm in the apical four-chamber view." The Settlement Agreement defines an abnormal left atrial dimension as a left atrial supero-inferior systolic dimension greater than 5.3 cm in the apical four chamber view or a left atrial antero-posterior systolic dimension greater than 4.0 cm in the parasternal long axis view. See id. § IV.B.2.c.(2)(b). Finally, Dr. Liston indicated that claimant's ejection fraction was "estimated to be 45%", which meets the definition of a reduced ejection fraction under the Settlement Agreement. See id.

In September 2002, the Trust forwarded the claim for review by Donna Zwas, M.D., one of its auditing cardiologists. In audit, Dr. Zwas concluded that there was no reasonable medical

basis for Dr. Liston's finding that claimant had moderate mitral regurgitation.⁴ In her Certification, Dr. Zwas stated that claimant's "[m]itral regurgitation is mild" and that she "reviewed the tape again on 5/9/03, and [claimant's] mitral regurgitation can only be described as mild."⁵

Based on Dr. Zwas' diagnosis of mild mitral regurgitation, the Trust issued a post-audit determination denying Ms. McCary's claim. Pursuant to the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit ("Audit Policies and Procedures"), claimant disputed this adverse determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7; PTO No. 2457, Audit Policies and Procedures § VI.⁶ The Trust then applied to

4. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). Dr. Zwas was not asked to review Dr. Liston's findings of an abnormal left atrial dimension or a reduced ejection fraction, both of which are qualifying complicating factors for a Level II claim. Thus, the only issue is claimant's level of mitral regurgitation.

5. Dr. Zwas' original review of claimant's echocardiogram was on September 30, 2002.

6. Claims placed into audit on or before December 1, 2002 are governed by the Audit Policies and Procedures, as approved in PTO No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Rules for the Audit of Matrix Compensation Claims, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Policies and Procedures contained in PTO No. 2457 apply to Ms. McCary's claim.

the court for issuance of an Order to show cause why Ms. McCary's claim should be paid. On April 30, 2003, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 2839 (Apr. 30, 2003).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on May 2, 2006. Under the Audit Policies and Procedures, it is within the Special Master's discretion to appoint a Technical Advisor⁷ to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Policies and Procedures § VI.J. The Special Master assigned Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant, and prepare a report for the court. The Show Cause Record and Technical Advisor's Report are now before the court for final determination. Id. at § VI.O.

The issue presented for resolution of this claim is whether claimant has met her burden in proving that there is a reasonable medical basis for the attesting physician's finding

7. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. U.S., 863 F.2d 149, 158 (1st Cir. 1988). In cases, such as here, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

that she had moderate mitral regurgitation. See id. at § VI.D. Ultimately, if we determine that there was no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. § VI.Q. If, on the other hand, we determine that there was a reasonable medical basis, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id.

In support of her claim, Ms. McCary submitted a "Limited Fen-Phen Echocardiogram Study" prepared by Robert Rosenthal, M.D., along with Dr. Rosenthal's curriculum vitae.⁸ Dr. Rosenthal also is no stranger to this litigation.⁹ In his study, Dr. Rosenthal quantified claimant's RJA/LAA ratio as 20%.

Claimant also submitted a certification prepared by Dr. Rosenthal. In his certification, Dr. Rosenthal stated, in pertinent part, that:

The degree of mitral regurgitation is 20% with the maximal jet documented at 16:52:52 recording time. This is an appropriately colored blue Doppler jet emanating from the mitral valve in systole. As per Green Form appendix end notes #3 and #5, the maximal regurgitant jet is expressed as a percentage of the left atrial area. The jet is confirmed by CW Doppler. Furthermore, the

8. We note that Dr. Rosenthal's "Limited Fen-Phen Echocardiogram Study" includes a disclaimer stating that: "[i]nterpretation of this study by the above named physician does not constitute a Doctor/Patient relationship."

9. The Trust submitted an affidavit, signed June 30, 2003, stating that Dr. Rosenthal had attested to 550 Green Forms as of May 31, 2003.

sonographer has documented the presence and extent of the mitral regurgitation jet with pulsed Doppler. The auditing cardiologist may be expressing his or her qualitative opinion of the degree of mitral regurgitation; however, the Settlement documents specify a scientific and quantitative degree of mitral regurgitation, a degree which is clearly substantiated by the echocardiogram.

Certification of Dr. Rosenthal ¶ 7 (attached as Exhibit 2 to Claimant's Show Cause Response).

Claimant also argues that the phrase "reasonable medical basis" means that an attesting physician's conclusions must be accepted unless the Trust proves they were "irrational or senseless from any medical perspective" and that an opinion lacks a reasonable medical basis only when it is "so slanted" that it exists outside the "present state of science." Claimant further argues that the auditing cardiologist did not follow the Settlement Agreement because he visually estimated her level of mitral regurgitation as opposed to taking actual measurements, which, in her view, are required by the Settlement Agreement.

In response, the Trust disputes claimant's characterization of the reasonable medical basis standard. Moreover, the Trust maintains, among other things, that the manner in which Dr. Zwas evaluated claimant's level of regurgitation complied with the Settlement Agreement and claimant

cannot meet her burden of proof simply by proffering an opinion from an additional cardiologist.¹⁰

The Technical Advisor, Dr. Vigilante, reviewed claimant's echocardiogram and determined that, at best, she only had mild mitral regurgitation. As explained by Dr. Vigilante:

Only trace mitral regurgitation was seen on color flow evaluation of the mitral valve in the parasternal long axis view. The apical two chamber view also demonstrated only trace mitral regurgitation. The apical four chamber view had very mild mitral regurgitation with a RJA/LAA ratio of less than 10%. "Real-time" evaluation of the tape never demonstrated significant mitral regurgitation. The recording time of 16:52:52 mentioned by Dr. Rosenthal in his Certification was not found. The times of 14:47 and 48 were noted when color flow was used to evaluate the mitral regurgitation jet in the apical two and four chamber views. Towards the end of the study, a still frame of the supposed mitral regurgitation jet was traced by the sonographer. However, this mitral regurgitation jet could not be found in real-time. In addition, low velocity non-mitral regurgitation flow was included in this tracing. This was an inaccurate tracing.

Dr. Vigilante further stated that: "only very mild mitral regurgitation was present" and "the RJA/LAA was less than 10%."

10. The Trust also argues that under Rule 26(a)(2) of the Federal Rules of Civil Procedure, physicians who proffer opinions regarding claims must disclose their compensation for reviewing claims and provide a list of cases in which they have served as experts. We disagree. We previously stated that Rule 26(a)(2) disclosures are not required under the Audit Policies and Procedures. See PTO No. 6997 (Feb. 26, 2007).

After reviewing the entire Show Cause Record, we find claimant's arguments all without merit. First, and of crucial importance, claimant does not contest the analysis provided by Dr. Vigilante.¹¹ Nor does claimant challenge Dr. Vigilante's specific finding that claimant's attesting physician relied on an inaccurate tracing. Claimant also does not refute Dr. Vigilante's conclusion that "[i]t would not be possible for a reasonable echocardiographer to conclude that any more significant mitral regurgitation than mild was present on this study." On this basis alone, claimant has failed to meet her burden of demonstrating that there is a reasonable medical basis for her claim.

We also disagree with claimant's definition of reasonable medical basis. Claimant relies on Gallagher v. Latrobe Brewing Co., 31 F.R.D. 36 (W.D. Pa. 1962) and Black's Law Dictionary, 1379 (5th ed. 1979), for determining what constitutes a reasonable medical basis. Such reliance, however, is misplaced. In Gallagher, the court addressed the situation where a court would appoint an impartial expert witness to be presented to the jury. See Gallagher, 31 F.R.D. at 38. Claimant also relies on the definition of "unreasonable" in Black's. The word "unreasonable" does not always mean "irrational" or "senseless"

11. Despite an opportunity to do so, claimant did not submit any response to the Technical Advisor Report. See Audit Policies and Procedures § VI.N.

as claimant would have us believe and does not mean that here. It can also be defined as "not guided by reason."

We are not persuaded that either Gallagher or Black's supports claimant's position. Instead, we are required to apply the standards delineated in the Settlement Agreement and the Audit Policies and Procedures. The context of these two documents leads us to interpret the "reasonable medical basis" standard as more stringent than claimant contends, and one that must be applied on a case-by-case basis. For example, as we previously explained in PTO No. 2640, conduct "beyond the bounds of medical reason" can include: (1) failing to review multiple loops and still frames; (2) failing to have a Board Certified Cardiologist properly supervise and interpret the echocardiogram; (3) failing to examine the regurgitant jet throughout a portion of systole; (4) over-manipulating echocardiogram settings; (5) setting a low Nyquist limit; (6) characterizing "artifacts," "phantom jets," "backflow" and other low velocity flow as mitral regurgitation; (7) failing to take a claimant's medical history; and (8) overtracing the amount of a claimant's regurgitation. See PTO No. 2640 at 9-15, 21-22, 26.

Here, Dr. Vigilante determined that the recording time referred to by Dr. Rosenthal in his certification could not be found on claimant's echocardiogram. Dr. Vigilante also noted that the still frame at the end of claimant's echocardiogram could not be found in real-time on the tape and that such study was traced inaccurately to include low velocity, non-mitral

regurgitation flow. Such unacceptable practices cannot provide a reasonable medical basis for the resulting diagnosis and Green Form answer of moderate mitral regurgitation.

Moreover, we disagree with claimant's arguments concerning the required method for evaluating a claimant's level of valvular regurgitation. Moderate mitral regurgitation is defined as "20%-40% RJA/LAA", which is based on the grading system required by the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). Although the Settlement Agreement specifies the percentage of regurgitation needed to qualify as having moderate mitral regurgitation, it does not specify that actual measurements must be made on an echocardiogram to determine the amount of a claimant's regurgitation. As we explained in PTO No. 2640, "'[e]yeballing' the regurgitant jet to assess severity is well accepted in the world of cardiology." See PTO No. 2640 at 15 (Nov. 14, 2002).

While claimant relies on the Settlement Agreement's use of the word "measured" in the definition of "FDA Positive", its meaning must be considered in the context of the phrase "by an echocardiographic examination", which immediately follows it. See Settlement Agreement § I.22.b. In its entirety, the phrase placed at issue by claimant is "measured by an echocardiographic examination." See id. The plain meaning of this phrase does not require actual measurements for assessing the level of mitral regurgitation. To the contrary, it means that a claimant's level of regurgitation must be determined based on an echocardiogram,

as opposed to other diagnostic techniques. Claimant essentially requests that we write into the Settlement Agreement a requirement that actual measurements of mitral regurgitation be made to determine if a claimant qualifies for Matrix Benefits. There is no basis for such a revision and claimant's argument is contrary to the "eyeballing" standards we previously have evaluated and accepted in PTO No. 2640.

Finally, we are not persuaded by Dr. Rosenthal's certification that Ms. McCary's claim is medically reasonable. As stated by Dr. Rosenthal, his opinion is based on one maximal jet, which allegedly appears at a recording time that was not found by the Technical Advisor on claimant's echocardiogram. Dr. Rosenthal believes that this jet was confirmed by continuous wave Doppler. Even if this alleged jet could be found, for a reasonable medical basis to exist, a claimant must demonstrate that a finding of the requisite level of regurgitation is representative of the level of regurgitation throughout an echocardiogram.¹² To conclude otherwise would allow claimants who do not have moderate or greater mitral regurgitation to receive Matrix Benefits, which would be contrary to the intent of the Settlement Agreement. Additionally, it is improper to rely

12. Under the Settlement Agreement, moderate or greater mitral regurgitation is defined as a "regurgitant jet area in any apical view equal to or greater than twenty percent (20%) of the left atrial area (RJA/LAA)." Settlement Agreement § I.22. Nothing in the Settlement Agreement suggests that it is permissible for a claimant to rely on isolated instances of what appears to be the requisite level of regurgitation to meet this definition.

on continuous wave Doppler to support a finding of regurgitation. As we stated in PTO No. 2640, "[n]owhere does the Green Form authorize the use of continuous wave Doppler to establish the severity or duration of mitral regurgitation." PTO No. 2640 at 18.

For the foregoing reasons, we conclude that claimant has not met her burden in proving that there is a reasonable medical basis for finding that she had moderate mitral regurgitation. Therefore, we will affirm the Trust's denial of both Ms. McCary's claim for Matrix Benefits and the related derivative claim submitted by her spouse.

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PRETRIAL ORDER NO.

AND NOW, on this 16th day of May, 2007, for the reasons set forth in the accompanying Memorandum, it is hereby ORDERED that the post-audit determination of the AHP Settlement Trust is AFFIRMED and that the Level II Matrix claims submitted by claimant Nellie McCary and her spouse, Philip McCary, are DENIED.

BY THE COURT:

/s/ Harvey Bartle III

C.J.